

**§ 558.435**

**21 CFR Ch. I (4–1–02 Edition)**

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992]

**§ 558.435 Oleandomycin.**

(a) *Approvals.* Type A medicated articles: 5 grams of activity per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.480 of this chapter.

(c) *Special considerations.* Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin. Oleandomycin refers to oleandomycin or feed-grade oleandomycin.

(d) *Conditions of use.* It is used in animal feed as follows:

(1) *Chickens and turkeys*—(i) *Amount per ton.* Oleandomycin, 1 to 2 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton.* Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 66 FR 47963, Sept. 17, 2001]

**§ 558.450 Oxytetracycline.**

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to 066104 in § 510.600(c) of this chapter.

(2) 50 and 100 grams per pound to 053389 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with § 558.5 labeling shall bear the statement: “FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.”

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C<sub>8</sub>–C<sub>18</sub>) trimethylammonium oxytetracycline

expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl (C<sub>8</sub>–C<sub>18</sub>) trimethylammonium oxytetracycline

expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d)(1) *Conditions of use.* It is used in feed as follows:

TABLE 1

| Oxytetracycline amount             | Combination | Indications for use  | Limitations  | Sponsor        |
|------------------------------------|-------------|--|--|----------------|
| (i) 10 to 20 grams per ton (g/ton) |             | Sheep; increased rate of weight gain and improved feed efficiency.                                     | .....  | 066104, 053389 |
| (ii) 10 to 50 g/ton                |             | 1. Chickens; increased rate of weight gain and improved feed efficiency.                               | Do not feed to chickens producing eggs for human consumption.  | Do.            |
|                                    |             | 2. Growing turkeys; increased rate of weight and improved feed efficiency.                             | Do not feed to turkeys producing eggs for human consumption.   | Do.            |
|                                    |             | 3. Swine; increased rate of weight and improved feed efficiency.                                       | .....  | Do.            |
| (iii) 100 g/ton                    |             | Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline. | Feed continuously for 7 to 14 days (d); do not feed to turkeys producing eggs for human consumption. | Do.            |

TABLE 1—Continued

| Oxytetracycline amount   | Combination                | Indications for use  | Limitations  | Sponsor        |
|--|----------------------------|--|--|----------------|
| (iv) 100 to 200 g/ton  | Salinomycin 40 to 60 g/ton | Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> ; control of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline.  | Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.                               | Do.            |
| (v) 200 g/ton  |                            | Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to oxytetracycline.  | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.   | 066104, 053389 |
| (vi) 400 g/ton   |                            | Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline.   | Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.                              | Do.            |
| (vii) 500 g/ton  |                            | Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline.  | Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter. | 066104, 053389 |
|  |                            | Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline; prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> . | .....do .....  | 012799, 066104 |
| (viii) 0.05 to 0.1 milligram/pound (mg/lb) of body weight daily. |                            | Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.   | Feed continuously; in milk replacers or starter feed.  | 066104, 053389 |
| (ix) 10 mg/lb of body weight daily.                              |                            | 1. Calves and beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline.   | Feed continuously for 7 to 14 d; in feed or milk replacers; withdraw 5 d before slaughter.   | Do.            |
|  |                            | 2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline.  | Feed continuously for 7 to 14 d; in milk replacers or starter feed; withdraw 5 d before slaughter.   | Do.            |
|  |                            | 3. Sheep; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.  | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.  | Do.            |

TABLE 1—Continued

| Oxytetracycline amount       | Combination | Indications for use  | Limitations  | Sponsor |
|------------------------------|-------------|--|--|---------|
| (x) 25 mg/lb of body weight  |             | 4. Swine; treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> susceptible to oxytetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.  | Do.     |
|                              |             | 5. Breeding swine; control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline.  | Feed continuously for not more than 14 d; withdraw 5 d before slaughter.   | Do.     |
|                              |             | Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.   | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption. | Do.     |
| (xi) 25 mg/head/day          |             | Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.  | .....  | Do.     |
| (xii) 75 mg/head/day         |             | Growing cattle (over 400 lb); increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.   | .....  | Do.     |
| (xiii) 0.5 to 2.0 g/head/day |             | Cattle; prevention and treatment of the early stages of shipping fever complex.  | Feed 3 to 5 d before and after arrival in feedlots.  | Do.     |
| (xiv) 200 mg/colony          |             | Honey bees; control of American foulbrood caused by <i>Bacillus larvae</i> and European foulbrood caused by <i>Streptococcus pluton</i> susceptible to oxytetracycline.  | Remove at least 6 weeks prior to main honey flow.  | Do.     |

(2) It is used in fish feed as follows:

TABLE 2

| Oxytetracycline amount                                    | Combination | Indications for use                            | Limitations   | Sponsor |
|---|-------------|--|---|---------|
| (i) 250 mg/kilogram of fish/d (11.35 g/100 lb of fish/d). |             | Pacific salmon for marking of skeletal tissue. | For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in feed containing oxytetracycline hydrochloride or mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of medicated feed. | 066104  |

TABLE 2—Continued

| Oxytetracycline amount               | Combination | Indications for use   | Limitations   | Sponsor |
|--------------------------------------|-------------|---|---|---------|
| (ii) 2.5 to 3.75 g/100 lb of fish/d. |             | 1. Salmonids; control of ulcer disease caused by <i>Hemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> , and pseudomonas disease. | Administer as mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 °C (48.2 °F).  | 066104  |
|                                      |             | 2. Catfish; control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and pseudomonas disease.   | Administer as mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F). | 066104  |
| (iii) 1 g/lb of medicated feed.      |             | Lobsters; control of gaffkemia caused by <i>Aerococcus viridans</i> .   | Administer as sole ration for 5 consecutive days in feed containing monoalkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline; withdraw medicated feed 30 d before harvesting lobsters.   | 066104  |

(3) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Robenidine hydrochloride in accordance with § 558.515.

(ii) Lasalocid as in § 558.311.

(iii) Melengestrol acetate as in § 558.342.

[61 FR 51590, Oct. 3, 1996, as amended at 63 FR 41192, Aug. 3, 1998; 66 FR 32740, June 18, 2001; 66 FR 45167, Aug. 28, 2001; 66 FR 47963, Sept. 17, 2001]

#### § 558.460 Penicillin.

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.

(b) *Sponsors.* Type A medicated articles: To 066104, 100 and 227 grams per pound. To 046573, 100 and 227 grams per pound.

(c) Related tolerances. See § 556.510 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

| Penicillin in grams per ton | Combination in grams per ton | Indications for use  | Limitations   | Sponsor         |
|-----------------------------|------------------------------|--|---|-----------------|
| (i) 2.4 to 50 .....         | .....                        | Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency.. | Do not feed to poultry producing eggs for human consumption.. | 000069, 046573. |
| (ii) 5 to 20 .....          | .....                        | Quail; for increased rate of weight gain and improved feed efficiency..                            | Quail; not over 5 weeks of age.                               | Do.             |
| (iii) 10 to 50 .....        | .....                        | Swine; for increased rate of weight gain and improved feed efficiency..                            | .....   | Do.             |